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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/015,399	01/29/98	HINKKANEN	A 2328-111

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HM12/0511

EXAMINER

LUBET, M

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

05/11/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/015,399

Applicant(s)

Hinkkahan

Examiner

Lubet

Group Art Unit

1644

☒ Responsive to communication(s) filed on May 22, 1998☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims☒ Claim(s) 1-17 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.☐ Claim(s) _____ is/are rejected.☐ Claim(s) _____ is/are objected to.☒ Claims 1-17 are subject to restriction or election requirement.**Application Papers**☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been☐ received.☐ received in Application No. (Series Code/Serial Number) _____☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☐ Notice of References Cited, PTO-892☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Supervisory Patent Examiner at Donald.Adams@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

1. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Group 1600 Group 1640 Art Unit 1644.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10 and 17 drawn to a fusion protein, cDNA encoding said fusion protein, and vector comprising said cDNA classified in class 435, subclasses 23.4 and 320.1, class 424, subclass 185 and class 530, subclass 403.
- II. Claims 11-15 drawn an immunoassay for simultaneous determination of a sample of diabetes mellitus related autoantigen utilizing the fusion protein of Group I, classified in class 435, subclass 7.1.
- III. Claim 16, drawn to a method of diagnosing a person's risk of developing diabetes by measuring autoantibodies to GAD, IA1 or PPINS, classified in class 435, subclass 7.1.

3. The inventions are distinct, each from the other because of the following reasons:

The proteins and nucleic acids of Group I and the immunoassay of Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the proteins of Group I can be used to elicit immune response, IE suppressor T cells or antibodies to the fusion protein.

The fusion proteins and nucleic acids of Group I and the immunoassay of Group II and the method of diagnosing risk of diabetes of Group III are unrelated. The method of diagnosing the

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risk of diabetes of Group III does not require the fusion protein of Group I or the immunoassay of Group II.

Because these inventions are distinct for the reasons given above and the researches required for Groups I-III are not coextensive, restriction for examination purposes as indicated is proper.

4. After the election of Groups I-III, a further election of species is required and the following requirement shall apply:

Currently, 1-17 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. The following is an example of an embodiment of Group I: a fusion protein according to claim 3 and cDNA encoding such a fusion protein.

6. If Applicant elect Group II, Applicant must elect a particular embodiment of the invention by electing a particular fusion peptide and a particular labeled reagent.

The following is an example of an embodiment of Group II: an immunoassay comprising the steps of

1) incubating the fusion protein of Claim 3

2). adding a labeled reagent wherein the labeled reagents comprises the fusion protein of claim 3 detectably labeled.

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7. If Applicant elects Group III, Applicant must elect a particular method of diagnosing by electing a particular embodiment of Group III. For instance, Applicant might elect a method of diagnosing diabetes by detecting autoantibodies to GAD65 and PPINS.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Martha Lubet in Art Unit 1644 whose telephone number is (703) 305-7148. The examiner can normally be reached on Monday through Friday from 8:15 AM to 4:45 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 3053973. The FAX number for this group is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Martha T. Lubet

TC
THOMAS M. CURNICKHAM
PRIMARY EXAMINER
GROUP 1800



RESTRICTION ELECTION FACSIMILE TRANSMISSION

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